K090888

510(k) Summary

Newport HT70™ Family of Ventilators

NOV 18 2009

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

The term "substantial equivalence" as used in this Premarket Notification is limited to the definition found in the Federal Food, Drug, and Cosmetic Act, 21 CFR 807, Subpart E, and relates only to whether the proposed device may be marketed without prior reclassification or clinical approval. This submission is therefore not related to the coverage of any patent and is not to be interpreted as admission or used as evidence in a patent infringement law suit or any other patent matters. [Reference Establishment Registration and Premarket Notification Procedures, Final Regulation, Preamble, August 23, 1977, FR 42520 (Docket No. 76N-0355).]

I. Submitter Information: Newport Medical Instruments, Inc.
1620 Sunflower Avenue
Costa Mesa, CA 92626

Contact Person: Dana Rodriguez
Vice President, RAQA

Summary Date: 27 March 2009

II. Device Name

Proprietary: To be determined.

Common: Ventilator, Continuous, Facility Use;
Continuous, Ventilator, Home Use

Classification: II

Product Code: CBK; NOU

CFR Section: 868.5895

III. Predicate Devices

The HT70 is substantially equivalent to the following legally marketed predicate devices:

- NEWPORT HT50® Ventilator cleared under K992133 and K082724;
- Pulmonetic Systems LTV® 1000 cleared under K981371, K984056, K002881, K010608, K032226, K040540, and K051767;
- Pulmonetic Systems PALMTop PTV Models 8/10 cleared under K070594; and
- Versamed Medical Systems iVENT™ 201 cleared under K981668, K011957, K021981, K042468, K052554, K053270, K061627, and K073694.

IV. Device Description

The Newport HT70 is a state of the art ventilator that combines ruggedness, exceptional mobility, and ease of use with clinical proficiency to provide ventilatory support for infant, pediatric and adult patients. It has a durable exterior and robust overall design that stands up to the harsh environments found in emergency response, transport and homecare environments. The HT70's unique design provides maximum mobility and safety for short or long distance transport of critically ill patients and also for patients who are going about their normal activities of daily life.

The HT70 is user friendly with all controls easily found on the front touchscreen and panel; there are no complicated menus or difficult sequences to follow in order to make necessary adjustments for common operations. It may be operated from AC or DC external power sources or from the "hot-swappable" Integrated Battery System. Any time the ventilator is connected to external power, the Integrated Battery System is charged, including while the ventilator is in use.

V. Intended Use

The Newport HT70 family of ventilators is intended to provide continuous or intermittent positive pressure mechanical ventilatory support for the care of individuals who require mechanical ventilation through invasive or non-invasive interfaces. Specifically, the Newport HT70 family of ventilators is applicable for infant, pediatric and adult patients greater than or equal to 5 kg (11 lbs).

The Newport HT70 is a restricted medical device intended for use by qualified, trained personnel under the direction of a physician.

The Newport HT70 is suitable for use in hospital, sub-acute, emergency room, and home care environments, as well as for transport and emergency response applications.

VII. Nonclinical Data

The Newport HT70 ventilator was subjected to a series of tests which address the following items:

- Electromagnetic Compatibility
- Electrical Safety
- Software and Hardware Verification and Validation.

All test results confirm the device to meet its design, performance, and safety specifications.

VIII. Clinical Data

No clinical or animal data were included in this submission.

IX. Conclusions

All testing demonstrates that the Newport HT70 performs as intended and has acceptable mechanical properties when used in accordance with its labeling; the device is therefore suitable for its intended use. As the device's intended use is

comparable to the referenced predicate devices, and its operating principles, ventilation modes and performance parameters are comparable to the predicate devices, the HT70 is substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room W-O66-0609
Silver Spring, MD 20993-0002

Ms. Dana Rodriguez
Vice President of Regulatory Affairs and Quality Assurance
Newport Medical Instruments, Incorporated
1620 Sunflower Avenue
Costa Mesa, California 92626

NOV 18 2009

Re: K090888
Trade/Device Name: Newport HT70™ Family of Ventilators
Regulation Number: 21 CFR 868.5895
Regulation Name: Continuous Ventilator
Regulatory Class: II
Product Code: CBK, NOU
Dated: October 29, 2009
Received: November 18, 2009

Dear Ms. Rodriguez:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for

Susan Runner, D.D.S., M.A.
Acting Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known):

Device Name: Newport HT70™ family of ventilators

Indications for Use:

The Newport HT70 family of ventilators is intended to provide continuous or intermittent positive pressure mechanical ventilatory support for the care of individuals who require mechanical ventilation through invasive or non-invasive interfaces. Specifically, the Newport HT70 family of ventilators is applicable for infant, pediatric and adult patients greater than or equal to 5 kg (11 lbs).

The Newport HT70 is suitable for use in hospital, sub-acute, emergency room, and home care environments, as well as for transport and emergency response applications.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

L Schultheiss

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K090884